REMARKS

I. Status

Claims 1-37 are pending and claims 17-37 are currently being prosecuted on the merits upon entry of the current amendment. Claims 17-19 are currently amended solely to clarify the subject matter for which protection is sought and to correct certain errors of a clerical nature, as discussed in greater detail below. No new matter is being added by the current amendments.

Applicants are currently adding new claims 20-22, which define various dosage ranges of clofarabine. Support for new claims 20-22 can be found throughout the specification, e.g., at page 14, lines 13-18. Applicants are also adding new claims 23-31, which define various immunomodulatory agents. Support for new claims 23-31 can be found throughout the specification, e.g., at page 11, lines 11-25. New claims 32-37 define various modes of administration, the support for which can be found throughout the specification, e.g., at page 15, lines 3-6.

Claims 18 and 19 are objected to due to an apparent clerical error. Claims 17 and 18 stand rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,384,310 ("the '310 patent"). Claim 19 stands rejected under 35 U.S.C. § 103(a) over the '310 patent in view of U.S. 5,491,229 ("the '229 patent"). Applicants traverse the rejections.

II. The Objection to Claims 18 and 19 Is Overcome

Claims 18 and 19 stand objected to because the term "insufficient" is misspelled. In the foregoing amendment to claims 18 and 19, the term "insufficient" is correctly spelled. As such, this objection is deemed overcome.

III. Claims 17 and 18 Are Novel

Claims 17 and 18 stand rejected under § 102(b) over the '310 patent. Applicants respectfully traverse this rejection.

Independent claim 17 as amended defines a pharmaceutical composition for the treatment of lupus which comprises clofarabine, or a pharmaceutically acceptable salt, hydrate, clathrate, solvate, prodrug, metabolite or stereoisomer thereof in a therapeutically effective amount for the treatment of lupus and a pharmaceutically acceptable carrier. The '310 patent does not anticipate claim 17 at least because it does not mention a pharmaceutical composition comprising clofarabine in a therapeutically effective amount for the treatment of lupus. Rather, the '310 patent at column 11, lines 14-16 mentions that its compounds may be administered in a regimen ranging from about 10 mg to 1000 mg per day. Such a regimen is not mentioned as being particularly useful for the treatment of lupus.

Contrary to the Examiner's assertion, material weight should be given to the preamble of claim 17. It is well settled that "a preamble limits the invention if it recites essential structure or steps, or *if it is 'necessary to give life, meaning, and vitality' to the claim.*" *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) citing *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). (emphasis added). Here, it is clear that the preamble of claim 17 gives "life and meaning" to the claim because the body of claim 17 as amended explicitly defines a therapeutically effective amount for the treatment of lupus. Claim 17 would not make sense if its preamble were not considered because the body of this claim specifically references lupus.

Claim 18 defines a pharmaceutical composition for the treatment of lupus which comprises a therapeutically effective amount of clofarabine, wherein the effective amount is sufficient to treat lupus and insufficient to cause adverse affects associated with purine nucleosides. The '310 patent does not anticipate claim 18 at least because it does not mention a dose of clofarabine that would be effective to treat lupus while avoiding adverse affects.

The use of the pharmaceutical compositions of claim 18 for the treatment of lupus connotes a structural limitation to the compositions insofar as the dosage amount of clofarabine for lupus does not necessarily correspond with the regimen mentioned in the '310 patent. Even if the range of the regimen of the '310 patent does overlap with the range defined by claim 18, which Applicants do not concede, the '310 patent does not provide sufficient specificity to a dose useful for the treatment as instantly defined. See MPEP § 2131.03 (8th Ed., Rev. 6). As such, the '310 patent does not anticipate claim 18.

In view of the foregoing remarks, removal of the present rejection is respectfully requested at this time.

IV. Claim 19 Is Not Obvious in view of the '310 Patent and the '229 Patent

Claim 19 stands rejected under § 103(a) over the '310 patent in view of the '229 patent. Applicants respectfully traverse this rejection because the Examiner has not satisfied the burden to establish a *prima facie* case of obviousness for at least the reasons presented below.

Claim 19 as amended defines a pharmaceutical composition for the treatment of lupus which comprises a therapeutically effective amount of clofarabine, wherein the effective amount is sufficient to treat lupus and insufficient to cause adverse affects associated with purine nucleosides,

a therapeutically effective amount of at least one other immunomodulatory agent and a pharmaceutically acceptable carrier. As such, the compositions defined by claim 19 comprise clofarabine and an immunomodulatory agent.

The Examiner concludes at page 5 of the Office Action that a person of ordinary skill in the art would have been motivated to arrive at the instant compositions of claim 19 because the '229 patent mentions at column 1, lines 61-66 that rapamycin has been found to have useful anticancer and immunomodulatory properties. Applicants respectfully submit that the Examiner's reasoning does not support such a motivation and thus a *prima facie* case of obviousness for a variety of reasons. One, the Examiner has not indicated how the '229 patent teaches or suggests the desirability of combining rapamycin with any anticancer agent, let alone clofarabine. Two, the Examiner has not indicted how the '229 patent teaches or suggests the desirability of treating lupus with such a combination. Three, the '229 patent does not reasonably lead a person of ordinary skill in the art to combine rapamycin with an anticancer agent just because rapamycin is supposedly useful as an anticancer agent and an immunomodulatory agent. Certainly, other reasons why the Examiner has not supported the *prima facie* case exist, but are not listed here for the sake of brevity.

In view of the foregoing discussion, it is apparent that the Examiner's reliance on *In re Kerkoven* is misplaced because neither the '310 patent nor the '229 patent teaches the use of clofarabine and rapamycin, respectively, as part of a pharmaceutical composition for the treatment of lupus. Rather, it is the instant application that teaches that clofarabine is useful for the treatment of lupus, and as the Examiner knows, relying on this teaching for obviousness under *Kerkoven* is impermissible. In addition, the '229 patent merely teaches that rapamycin has immunomodulatory properties. Those of skill in the art reading the '229 patent would not readily be lead to treating

lupus. Thus, Applicants respectfully request the Examiner remove the instant rejection for the foregoing reasons.

V. Conclusion

Having addressed all outstanding issues, Applicants kindly request removal of all rejections and allowance of all pending claims at this time. To the extent the Examiner believes that it would facilitate allowance of this case, the Examiner is urged to call the undersigned at the number below.

Applicants believe a fee is associated with the filing of this paper. The Commissioner is hereby authorized by this paper to charge any required fees or credit any overpayment to Deposit Account 07-1074.

Respectfully submitted,

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